

Rec'd PCT/PTO 19 APR 2002

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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | Attorney Docket No. 02075 |
| | | U.S. Application No. (if known) 10/089102 |
| INTERNATIONAL APPLICATION NO. PCT/GB00/04087 | INTERNATIONAL FILING DATE October 23, 2000 | PRIORITY DATE CLAIMED October 21, 1999 |
| TITLE OF INVENTION IMPLANT ALIGNMENT | | |
| APPLICANT(S) FOR DO/EO/US Ashok Sethi & Peter Sochor | | |
| Applicant herewith submits to the United States Designated Office (DO/EO/US) the following items and other information: | | |
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). 4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). b. <input checked="" type="checkbox"/> has been transmitted by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)). <ol style="list-style-type: none"> a. <input type="checkbox"/> are transmitted herewith (only if not required by the International Bureau). b. <input type="checkbox"/> have been transmitted by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). | | |
| Items 11 to 16 below concern document(s) or information included: | | |
| <ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> As assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <ol style="list-style-type: none"> <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 14. <input type="checkbox"/> A substitute specification. 15. <input type="checkbox"/> A change of power of attorney and/or address letter. 16. <input type="checkbox"/> Other items or information: | | |



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PATENT TRADEMARK OFFICE

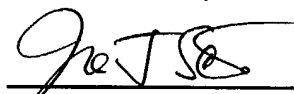
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| 17. <input checked="" type="checkbox"/> The following fees are submitted: | | | | CALCULATIONS PTO USE ONLY | |
| BASIC NATIONAL FEE (37 CFR 1.492 (a)(1)-(5): | | | | | |
| Neither international preliminary examination fee (37 CFR 1.482) | | | | | |
| Nor international search fee (37 CFR 1.445(a)(2) paid to USPTO | | | | | |
| And International Search Report not prepared by EPO or JPO..... \$1,040.00 | | | | | |
| International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by EPO or JPO.....\$890.00 | | | | | |
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| International preliminary examination fee paid to USPTO (37 CFR 1.482) But all claims did not satisfy provisions of PCT Article 33(1)-(4).....\$710.00 | | | | | |
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| ENTER APPROPRIATE BASIC FEE AMOUNT = | | | | \$890.00 | |
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| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total Claims | 8 -20= | | X \$18.00 | \$ | |
| Independent Claims | 1 -3= | | X \$84.00 | \$ | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | | \$ | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$1020.00 | |
| Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28). | | | | \$510.00 | |
| SUBTOTAL = | | | | \$510.00 | |
| Processing fee of \$130.00 for furnishing English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f). | | | | \$ | |
| TOTAL NATIONAL FEE = | | | | \$510.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). | | | | \$ | |
| TOTAL FEES ENCLOSED = | | | | \$510.00 | |
| | | | | Amount to be refunded: | \$ |
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- a. ☒ A check in the amount of \$510.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. 04-0753 in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-0753. A duplicate copy of this sheet is enclosed.
- d. ☐ A payment of \$ _____ is made by credit card. A Credit Card Payment Form (PTO-2038) is attached hereto. The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 CFR 1.16 or any patent application processing fees under 37 CFR 1.17, or credit any over payment to the credit card account shown on the attached Credit Card Payment Form. Refund of all amounts overpaid, including those of twenty-five dollars or less, is specifically requested. Any fees not accepted by the credit card shown on Form PTO-2038 may be charged to Deposit Account No. 04-0753.

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SIGNATURE

Ira J. Schultz

NAME

28666

REGISTRATION NUMBER

90 Rec'd PCT/PTO 30 MAY 2002

Dkt. 02075

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Group Art Unit:

ASHOK SETHI et al

Examiner:

Serial No.: 10/089,102

Filed: April 19, 2002

For: IMPLANT ALIGNMENT

SECOND PRELIMINARY AMENDMENT

Honorable Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Please amend the above-identified application as follows:

IN THE CLAIMS:

Please cancel claims 1-8 without prejudice or disclaimer of the subject matter thereof, and add the following new claims:

10. (New) Apparatus for alignment of a dental prosthesis,
said apparatus comprising:

an implant for insertion in the jaw bone of a patient,
the implant having a generally axial bore;

a plurality of angled templates for use with said implant, each of said templates having a circular cross section locator lug for inter-engagement with the axial bore

of the implant; and

an abutment to which the prosthesis is formed;

wherein said plurality of templates are provided in a range of angles from 5° to 45°, whereby in use one of said templates is selected for use in determining which abutment to use, the selection of said one template being made on the basis of a correct orientation of an alignment element thereof relative to the existing teeth of the patient.

11. (New) Apparatus according to claim 10, wherein the locator lug comprises a frusto-cone having a portion of smaller diameter towards a free end of the lug.

12. (New) Apparatus according to claim 11, wherein the locator lug further comprises an extension piece extending generally axially along an axis of the frusto-cone.

13. (New) Apparatus according to claim 12, further comprising a plurality of driving flats disposed about a mouth of the template bore and adapted for inter-connection with corresponding elements on the implant.

14. (New) Apparatus according to claim 11, wherein the frusto-cone is additionally provided with a plurality of driving flats.

15. (New) Apparatus according to claim 10, wherein the template comprises a shaft remote from the locator lug, said shaft being adapted to mimic the angle of existing teeth when

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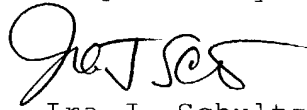
inserting an implant in the jaw bone of a patient, the
implant having a generally axial bore;

selecting one of said templates for use in determining which abutment to use, the selection of the template being made on the basis of a correct orientation of an alignment element thereof relative to the existing teeth of the patient.

REMARKS

A new set of claims has been added for initial examination, the new claims corresponding to the claims attached to the International Preliminary Examination Report.

Respectfully submitted,



Ira J. Schultz
Registration No. 28666

Dkt. 02075

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Group Art Unit:

ASHOK SETHI et al

Examiner:

Serial No.: US National Phase of
PCT/GB00/04087

Filed: concurrently herewith

For: IMPLANT ALIGNMENT

PRELIMINARY AMENDMENT AND INFORMATION DISCLOSURE STATEMENT

Honorable Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Before calculation of the filing fee, please amend the
above-identified application as follows:

IN THE ABSTRACT:

Please add the following abstract:

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703 412-1155

ABSTRACT OF THE DISCLOSURE

An apparatus for alignment of dental implants in which an implant is provided with a generally axial bore and a plurality of angled templates, each adapted for operative inter-connection with the bore of the implant. Each template includes a locator lug adapted for inter-engagement with the axial bore of the implant, each lug having a circular cross-section.

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IN THE CLAIMS:

Please amend the claims as set forth hereinbelow and in the attached appendix:

3. (Amended) An apparatus according to claim 1 wherein the locator lug is separate from the template and the template is provided with a bore which is adapted to be generally coaxial with the bore of the implant in use.

4. (Amended) An apparatus according to claim 1 wherein the locator lug is a frusto-cone having its portion of smaller diameter towards the free end of the lug.

7. (Amended) An apparatus according to claim 4 wherein the frusto-cone is additionally provided with a plurality of driving flats.

8. (Amended) An apparatus according to claim 1 wherein the template comprises a shaft remote from the locator lug, said shaft has been adapted to mimic the angle of existing teeth when rotated.

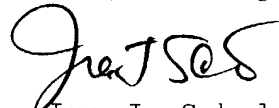
Please cancel claim 9 without prejudice or disclaimer of the subject matter thereof.

REMARKS

The claims have been amended to delete all multiple dependencies.

Attached is the search report of the corresponding PCT application, together with copies of the references cited therein, which are listed on the attached Form PTO-1449.

Respectfully submitted,



Ira J. Schultz
Registration No. 28666

APPENDIX

3. (Amended) An apparatus according to [either claims] claim 1 [or 2] wherein the locator lug is separate from the template and the template is provided with a bore which is adapted to be generally coaxial with the bore of the implant in use.

7. (Amended) An apparatus according to [any of claims 4 to 6] claim 4 wherein the frusto-cone is additionally provided with a plurality of driving flats.

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10/089102

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IMPLANT ALIGNMENT

The present invention relates to the alignment of dental implants and to a method for their alignment. In the Probe, 5 September 1998, I have described a dental implant and a method for its insertion. In this arrangement a site is selected so that it is in the middle of a ridge. The jaw bone is drilled using internally irrigated titanium alloy burs so that it is sited between the labial and palatal cortical plates, making 10 sure that the adjacent teeth and anatomical structures are avoided. The implant is inserted until level with the bone.

Abutment or template selection is effected by using a trial 15 abutment (template) which measures the restorative angle, allows the implant to be positioned to the correct depth, and aligns the driving flat (or hex) in the correct plane.

The trial abutment (template) should fit within the hollow 20 prosthetic envelope. This ensures that the final abutment will be in the right position. Any adjustments to the position of the implant can now be made before it is integrated. The cover screw is then replaced, the wound is sutured and the implant is allowed to integrate over a period 25 of about six months.

The depth to which the implants are placed is important since if they are too deep this may result in bone loss (to the 1st thread) which is not ideal, and if they are not deep enough 30 they may become exposed prematurely. That a trial abutment or template is necessary is shown by the fact that otherwise there is no way that the angle of the abutment can be selected and the plane of orientation measured or changed unless this

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is done at the 1st stage of surgery.

In order to achieve this, previously each template was provided with a downwardly depending lug provided with a plurality of driving planes for co-operation with similarly shaped receptor planes in the corresponding bore in which it was adapted to fit. Said "internal hex" arrangements can be satisfactory but give rise to a number of problems. In the first place the internal driving planes have to be small and therefore their manufacture is relatively difficult. However because they can be subjected to significant rotational forces during positioning the manufacturing tolerances must be of a low order. Most of all the utilisation of the internal driving flats, as previously suggested raises the difficulty that the dentist cannot be sure that the template is fully "home" on the implant, which can give rise to misalignments once full implant integration has occurred.

The need therefore exists for a template which will drive the implant during rotation only if the template and the implant are fully engaged. Further there is a need to ensure that the turning moment applied by the template to the implant is as positive as possible.

According to the present invention there is provided an apparatus for the alignment of a dental implant, said apparatus comprising an implant comprising a generally axial blind bore and a plurality of angled templates each adapted for operative inter-engagement with the bore of the implant; characterised in that each template comprises a locator lug for inter-engagement with the axial bore of the implant, said lug comprising a circular cross-section. It is preferred that the lug shall have a frusto-conical section for inter-

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engagement with a corresponding bore in the implant (or taper-lock). In a further embodiment the frustro-conical section includes a plurality, preferably four, of driving planes for co-operation with the bore of the implant. It is also preferred that the frusto-conical section terminates towards its free end in a portion of a smaller diameter.

Alternatively the locator lug may be of a right cylindrical configuration and a plurality of driving planes are provided internally of the body of the template for operative interconnection with a corresponding set of driving flats positioned about the mouth of the bore of the implant.

In an alternative arrangement the locator lug is separate from the template and the template is formed with a bore that is adapted to be co-axial in use with that of the implant.

In a preferred embodiment the template terminates at its intended upper end remote from the lug in a shaft or peg which has a generally elongate configuration, often of a right cylindrical shape, so that whatever its rotational position it will mimic the correct angle of the existing teeth in use.

By means of the present invention the implant will only rotate to its final position when fully inter-engaged. Partial inter-engagement, and hence misalignment of the template with the implant, is thus much less likely to occur.

The invention will now be described, by way of illustration only, with reference to the accompanying drawings wherein:-
Figure 1 shows a side view from below of a first template of the invention;

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Figure 2 shows a side view from below of a final abutment for use with the invention;

Figure 3 shows a side view of the first template in cross-section;

5 Figure 4 shows a side view from below of another template of the invention;

Figure 5 shows a side view a template somewhat as shown in Figure 1 but with a plurality of driving planes disposed in frusto-conical portion.

10 Figure 6 shows an exploded side view of a template with a frusto-conical lug in part vertical section;

Figure 7 shows a side view in part section of a template with locking flats to form a external "hex" on the implant;

Figure 8 shows an exploded side view in part section of a
15 template and implant in accordance with Figure 2,

Figure 9 shows a side view part section of the arrangement of Figure 4, and

Turning first to Figures 1 to 4, Figure 1 shows a template
20 comprising a main body which is generally angled to the axis of an implant.

A template alignment shaft 3 and body 4 are angled to the axis of the implant in use by an amount varying from 5° and 45°
25 degrees. The template and the implant are arranged such that they are correctly positionable prior to integration relative to a bore positioned in the jaw by means of the correct orientation of the shaft 3 relative to the existing teeth in use.

30

As is shown in Figure 1, the body of the template 1 terminates in generally downwardly depending frusto-conical portion 5 and a right cylindrical extension piece 6. It is arranged

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An exploded diagram of the implant and template assembly according to the present invention, somewhat as shown in Figure 2, is shown in Figure 6. In this arrangement, shown in partial cross-section, a threaded bolt 18 is provided with an Allen key aperture 19 and is adapted for location in an upper bolt aperture 7. The shaft of the bolt 18 passes through the frusto-conical portion of the template 5 and through the lower bolt aperture 8.

10 With the implant and the template fully inter-engaged, the threaded end of the bolt 18 enters a recess 16 in the implant 2. Implant 2 is provided to its exterior with a ribbed edged body 14 terminating towards its upper edge in an annular implant head 13. At its other (lower) end is a cut out 15 for reasons of bone integration.

In use the bolt 18 secured in the aperture 7 passes into the recess 16 and into the screw thread cavity 17, whereupon rotation of the Allen key in aperture 19 causes the template 1 to lock onto the implant 2 in a temporary fashion. The Allen key can then be used to rotate the template 1 into its correct orientation relative to other teeth. The bolt 18 then may be withdrawn without disturbing the implant 2 and the template 1 may be removed and recorded.

25 A similar arrangement is shown in Figure 7 but in this instance bolt 18 is provided with standard external driving flats 18', while the template 1 is provided with internal driving flats 10 only.

30 In Figure 8 there is provided an exploded arrangement showing in part section an embodiment of Figure 3. Its *modus operandi* has been fully described with regard to Figure 6. The only

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Claims

1. Apparatus for use in the alignment of a dental
5 prosthesis, said apparatus comprising:-
 an implant (2) for insertion in the jaw bone of a
 patient, the implant having a generally axial bore (17);
 a plurality of angled templates (1) for use with said
10 implant, each one of said templates having a circular cross-
section locator lug (6) for inter-engagement with the axial
bore of the implant; and
 an abutment to which the prosthesis is formed;
 wherein said plurality of templates (1) are provided in
a range of angles from 5° to 45°, whereby in use one of said
15 templates is selected for use in determining which abutment
to use, the selection of said one template being on the basis
of a correct orientation of an alignment element thereof
relative to the existing teeth of the patient.
- 20 2. Apparatus according to claim 1 wherein the locator lug
comprises a frusto-cone having its portion of smaller
diameter towards the free end of the lug.
3. Apparatus according to claim 2 wherein the locator lug
25 further comprises an extension piece extending generally
axially along the axis of the frusto-cone.
4. Apparatus according to claim 3 further comprising a
plurality of driving flats disposed about the mouth of the
30 template bore and adapted for inter-connection with
corresponding elements on the implant.
5. Apparatus according to any of claims 2 to 4 wherein the

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frusto-cone is additionally provided with a plurality of driving flats.

6. Apparatus according to any preceding claim wherein the
5 template comprises a shaft remote from the locator lug, said shaft has been adapted to mimic the angle of existing teeth when rotated.

7. A system for use in the alignment of a dental prosthesis,
10 said system comprising:-

inserting an implant (2) in the jaw bone of a patient, the implant having a generally axial bore (17);

providing a plurality of angled templates (1), for use with said implant, each one of said templates having a
15 circular cross-section locator lug (6) for inter-engagement with the axial bore of the implant and wherein said plurality of templates (1) are provided in a range of angles from 5° to 45°;

selecting one of said templates for use in determining
20 which abutment to use, the selection of the template being on the basis of a correct orientation of an alignment element thereof relative to the existing teeth of the patient.


 DATABASE UPDATED

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

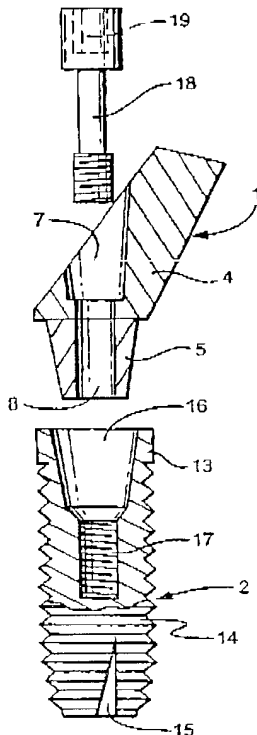
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(10) International Publication Number
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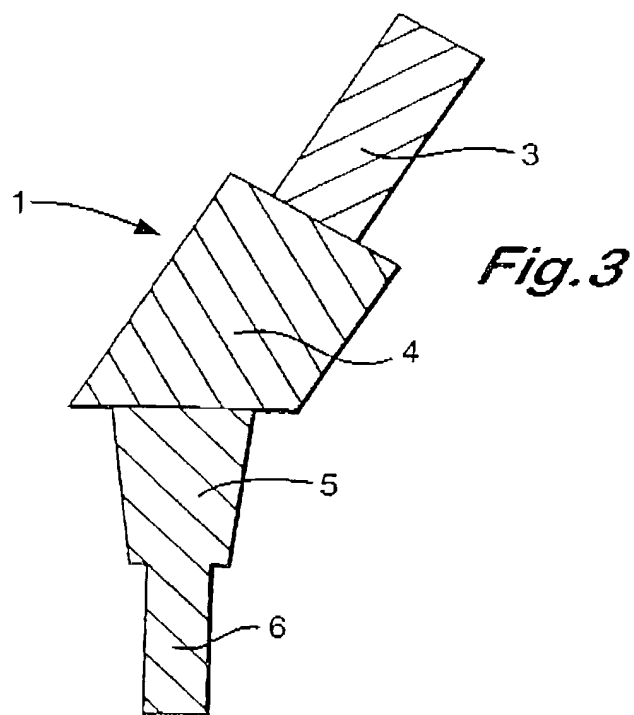
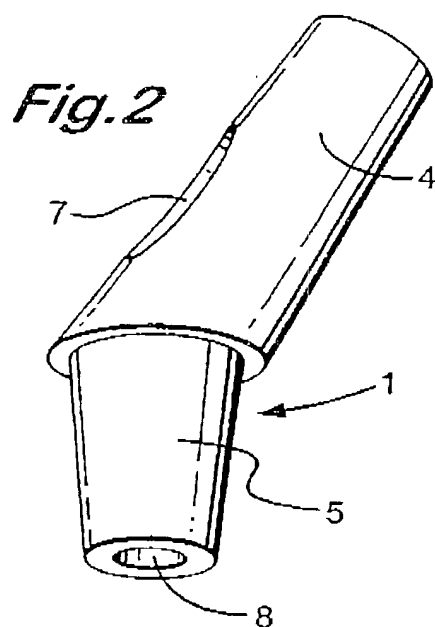
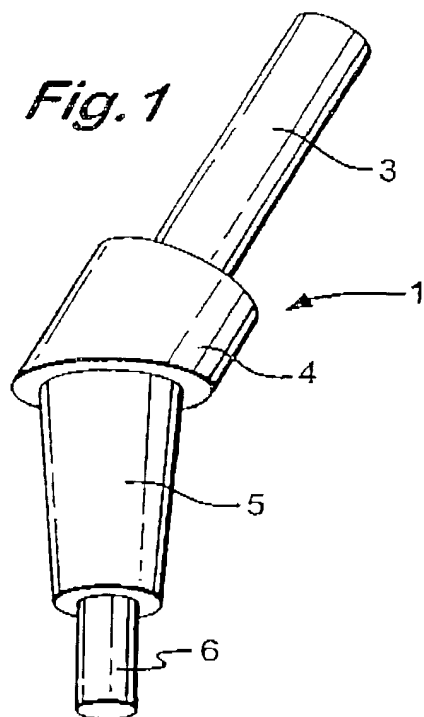
- (51) International Patent Classification⁷: A61C 8/00 (74) Agents: SUER, Steven, Johannes et al.: Ahlert & Stebbing, Caparo House, 101-103 Baker Street, London W1M 1FD (GB).
- (21) International Application Number: PCT/GB00/04087
- (22) International Filing Date: 23 October 2000 (23.10.2000) (81) Designated State (*national*): US.
- (25) Filing Language: English
- (26) Publication Language: English (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- (30) Priority Data:
9924959.1 21 October 1999 (21.10.1999) GB Published:
— With international search report.
- (71) Applicants and
(72) Inventors: SETHI, Ashok [GB/GB]; 33 Harley Street, London W1N 1DA (GB) SOCHOR, Peter [GB/GB]; 125 Imperial Drive, Harrow HA2 7HW, Middlesex (GB).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: IMPLANT ALIGNMENT



(57) Abstract: The present invention relates to apparatus for the alignment of dental implants, said apparatus comprising an implant (2) provided with a generally axial bore and a plurality of angled templates (1) each adapted for operative interconnection with the bore of the implant. Each template comprises a locator lug adapted for inter-engagement with the axial bore of the implant, said lug comprising a circular cross-section.

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Fig. 4

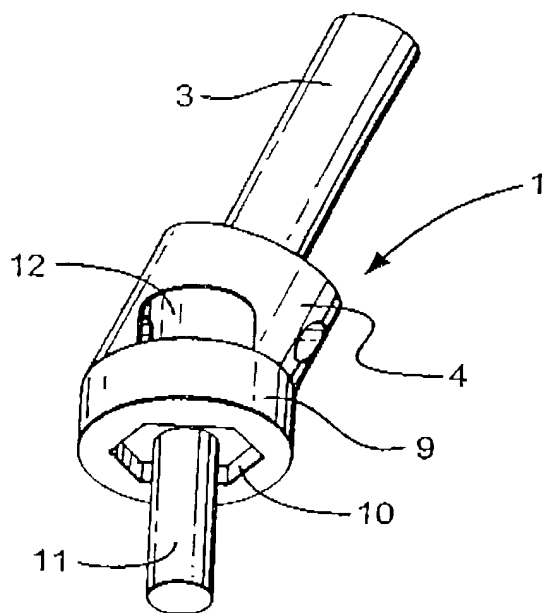
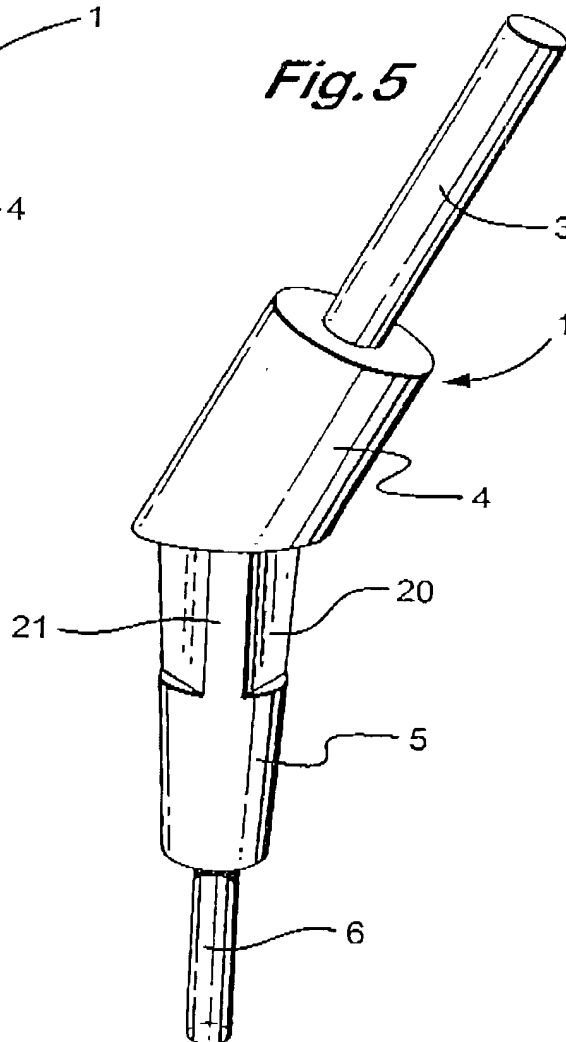


Fig. 5

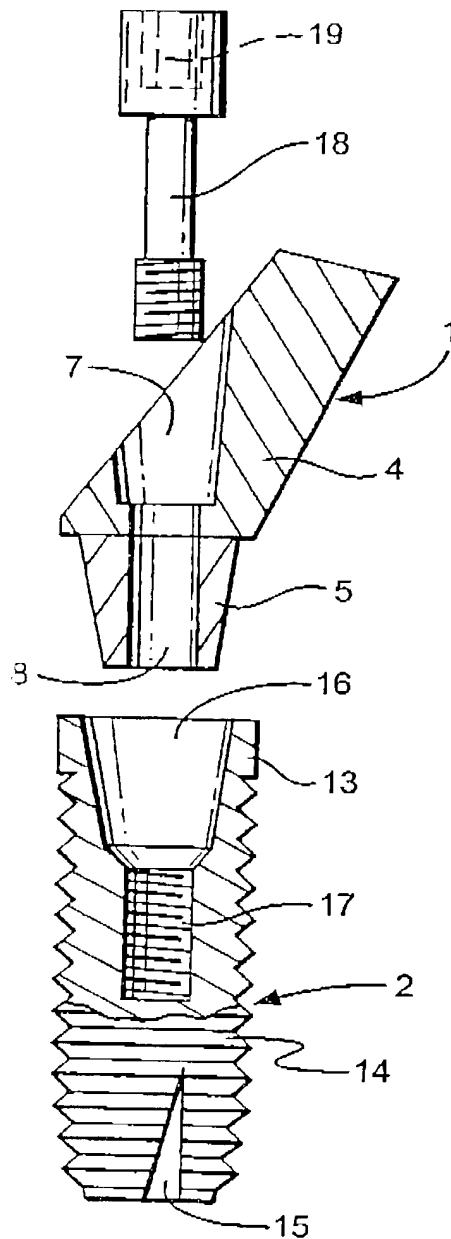
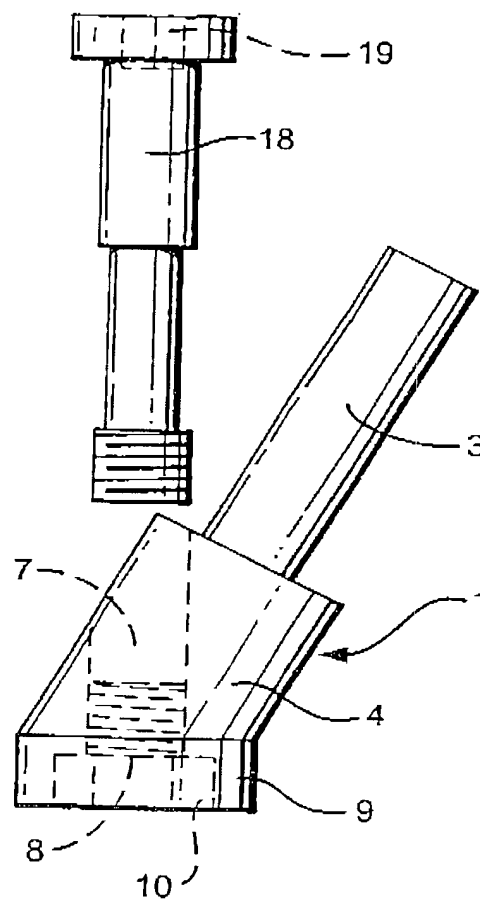


SUBSTITUTE SHEET (RULE 26)

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Fig. 6*Fig. 7*

SUBSTITUTE SHEET (RULE 26)

Fig. 8

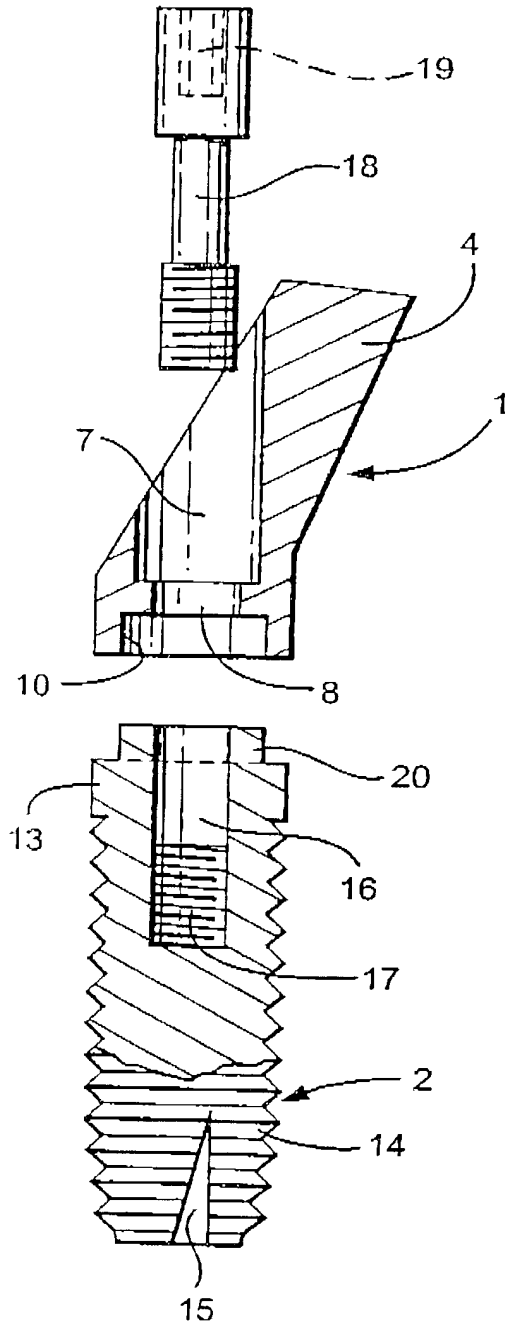
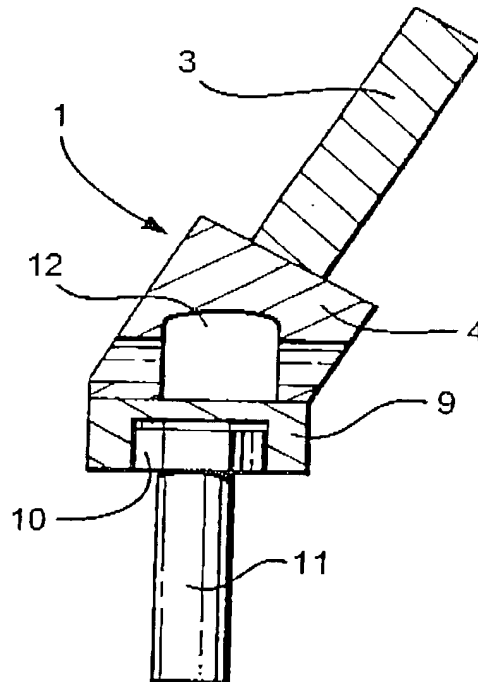


Fig. 9



DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

Docket No. 02075

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

IMPLANT ALIGNMENT

specification of which

(check one) XX is described and claimed in PCT International Application PCT/GB00/04087 filed on (MM/DD/YYYY) Oct. 23, 2000, amended on Apr. 19, 2002 (if applicable)

(OR) _____ is described in United States Application Number _____ filed on (MM/DD/YYYY) _____ (OR) _____ is attached hereto.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Claimed? Yes No |
|-------------------------------------|---------------|----------------------------------|--------------------------|
| 9924959.1 | Great Britain | October 21, 1999 | XX |
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I hereby claim the benefit under 35 U.S.C. 119(e) of any United States Provisional Application(s) listed below.

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I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s), or 365(c) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

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As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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